**General Correspondence**
**Comments on FDA's Draft Guidance**


May 27, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**RE: Docket No. 2005D-0103**
**Draft Guidance for Industry on Using a Centralized Institutional Review Boards Process in Multicenter Clinical Trials**

Dear Sir/Madam:

Novo Nordisk Inc. appreciates the opportunity to provide comments to the above-captioned docket on the Draft Guidance for Industry on Using a Centralized Institutional Review Boards Process in Multicenter Clinical Trials. Novo Nordisk is a pioneer in biotechnology and a world leader in diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems. In addition, Novo Nordisk has a leading position within areas such as hemostasis management, growth hormone therapy, and hormone therapy for women. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to our patients' lives, the medical profession and society.

Novo Nordisk fully supports FDA's initiative to reduce IRB burdens and delays in the conduct of multicenter trials by proposing a strategy to implement a centralized IRB review process for these trials. We believe that this draft guidance will help sponsors, institutions, IRBs and clinical investigators involved in multicenter clinical research meet the requirements of 21CFR Part 56 by facilitating the use of a centralized IRB review process.

The draft guidance as written provides comprehensive guidelines on implementing a centralized IRB review process for multicenter trials. However, for additional clarity, we propose that a statement be added to Section IV (Addressing Local Aspects of IRB Review) indicating it is recommended that the institution be responsible for deciding whether a central IRB can meet local community needs. Section IV discusses possible mechanisms to ensure meaningful consideration of relevant local factors but does not address who should consider the ethical standards of the local community.

In summary, Novo Nordisk supports FDA's initiative in providing guidance to help facilitate IRB review of multicenter trials using a centralized IRB review process and thereby improve efficiency with the process and reduce IRB burdens.

Sincerely,

Novo Nordisk Inc.

Janet M. Onthank FOR

Mary Ann McElligott, Ph.D.
Associate Vice President,
Regulatory Affairs